



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,923	11/25/2003	Janet Codd	102458-40933 (Nascime 2)	8326
996	7590	01/11/2006	EXAMINER	
GRAYBEAL, JACKSON, HALEY LLP 155 - 108TH AVENUE NE SUITE 350 BELLEVUE, WA 98004-5901			KIM, JENNIFER M	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,923	CODD ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The reply filed October 20, 2005 have been received and entered into the application.

It is noted that some minor informalities in the reply wherein the structure of the compound of formula set forth in the claims, particularly claim 12 is un-identifiable. There is typographical error in claim 12, line 7; the term "composition 11" should be "composition". Appropriate correction is required.

Action Summary

The rejection of claims 12-21 under 35 U.S.C. 103(a) as being unpatentable over Media Release (November 4, 2002) in view of Hirsh et al. (US 2003/0035839 A1) is being maintained for the reasons stated in the previous office action.

Response to Arguments

Applicants' arguments filed October 20, 2005 have been fully considered but they are not persuasive. In response to applicant's argument that there is no information is included in the subject Media Reporting pertaining a dosage form of ocinaplon

Art Unit: 1617

comprising two separate compartments each containing ocinaplon with specific amounts with rapid release in first compartment and sustained release in second compartment with hydrophilic polymeric matrix, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the active agent, ocinaplon, is well known to be formulated in controlled-release formulation and having useful utility in the treatment of generalized anxiety disorders as well taught by Media Release, and Hirsh et al. teach the formulation of anxiolytic in two different portions having same active agent in both portions in delayed release is old and well known. Therefore, it would have been obvious to one of ordinary skill in the art to modify the controlled-release ocinaplon of Media Release formulated in any known formulation of anxiolytic including two different portions in a delayed release formulation well-known by Hirsh et al. without a surprising and unexpected result. It is suggested that Applicants submit a declaration to clearly establish a surprising and unexpected result using Applicants teaching.

In view of the above, the Office Action of June 17, 2003 is deemed proper and asserted with full force and effect herein to obviate applicants' claims. The rejections are restated below for the Applicants' convenience.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in prior Office Action.

Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Media Release (November 4, 2002) in view of Hirsh et al. (US 2003/0035839 A1).

Media Release announces positive phase II results for ocinaplon as a novel anti-anxiety product in its therapeutic use for generalized anxiety disorders. (title). Media Release teaches that ocinaplon is a non-benzodiazepine that exhibits anxiolytic-like effects in animal studies as a similar pharmacological profile to anxiolytic benzodiazepines. Media Release teaches controlled-release ocinaplon administered twice or three times a day is effective in the treatment of patients with generalized anxiety disorders. Media Release teaches ocinaplon was administered orally 60mg three times a day or 120mg twice a day for 14 days. (Content).

Media Release does not teach the two separate compartments each containing ocinaplon with specific amounts with rapid release in first compartment and sustained release in second compartment with hydrophilic polymeric matrix (hydroxypropyl methyl cellulose) in a unit dose, carriers such as lactose and a particle size.

Hirsh et al. teach new pharmaceutical composition in unit dosage form comprising anxiolytic in two different portions comprising immediate (outer layer) as well as sustained release (core). (abstract, [0012], [0014], [0028], [0038]-[0042]). Hirsh et

Art Unit: 1617

al. teach that the inner core of the composition can be formulated as a delayed release coating with hydroxypropyl methylcellulose. ([0060]). Hirsh et al. teach that the core of the composition can be formulated with inert carrier such as lactose. ([0031]). Hirsh et al. teach that the active ingredient of the composition may be the same pharmaceutically active ingredient. ([0014]). Hirsh et al. teach that the composition provides immediate as well as sustained and prolonged therapeutic benefit and improves compliance. ([0016]-[0012]).

It would have been obvious to one of ordinary skill in the art to modify the controlled-release ocinaplon of Media Release to the composition in unit dosage form comprising two portions as taught by Hirsh et al. One would have been motivated to make such a modification in order to achieve the advantage of two portion comprising immediate as well as sustained release to improve prolonged therapeutic benefit and improve the compliance as taught by Hirsh et al. It would have been obvious to one of ordinary skill in the art to employ hydroxypropyl methyl cellulose in delayed release coating since Hirsch et al teaches that the hydroxypropyl methyl cellulose is useful in delayed release portion as a coating. One would have been motivated to make such a modification with a reasonable expectation of successfully coating delayed portion with hydroxypropyl methyl cellulose as taught by Hirsch et al. The amounts of active agent (ocinaplon) to be used in each portion, the pharmaceutical carriers (e.g. lactose), and the particle size are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and each portion can be formulated with same active agent contained therein and the utilization of lactose as a carrier is well taught by Hirsch et al.

Art Unit: 1617

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

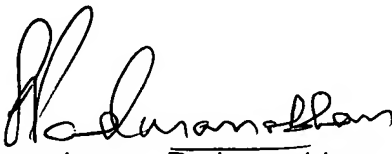
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
December 28, 2005